Zimmer
MedizinSysteme

Zimmer Medizinsysteme GmbH
Junkersstraße 9
D-89231 Neu-Ulm

Tel. 0731 / 9761-0
Fax 0731 / 9761-118

info@zimmer.de
www.zimmer.de

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5. 510(k) Summary

The following information is provided as required in 21CFR807.87 and the Guidance Document "Guidance Document for Powered Muscle Stimulators 510(k)s"

a.) General

510(k) Submitter:
Zimmer MedizinSysteme GmbH
Junkersstrasse 9
D-89231 Neu-Ulm
Germany

Contact person:
Mr. Armin Petraschka
Project Manager
Phone: +49-731-9761-140
Fax: +49-731-9761-4475
E-mail: a.petraschka@zimmer.de

Establishment Registration: 8010720

Submission Date: January 13th, 2012

Device Names:

Device family name:	Soleoline
Trade Names:	Soleo Stim
	Soleo Sono
	Soleo SonoStim
Common Names:	Ultrasound and muscle stimulator
	Powered muscle stimulator
	Transcutaneous electrical nerve stimulator for pain relief
	Ultrasonic diathermy

Regulation Numbers and Classification Names:
21 CFR 890.5850 – Stimulator, Muscle, Powered
21 CFR 890.5300 – Ultrasonic diathermy
21 CFR 890.5860 – Ultrasound and muscle stimulator
21 CFR 882.5890 – Transcutaneous electrical nerve stimulator for pain relief

Classification: Class II

Product Codes: IPF, IMI, IMG, GZJ

Panel:
89 – Physical Medicine
84 – Neurology

b.) Predicate Devices

1.

Device:	Vectra Genisys
Manufacturer:	CHATTANOOGA GROUP (Encore Medical) 4717 adams rd. P.O. Box 489 Hixson, Tennessee 37343-0489
510(k) number:	K031077

2.

Device:	Galva 5 M
Manufacturer:	Zimmer MedizinSysteme GmbH (former Zimmer Elektromedizin GmbH) Junkersstrasse 9 89231 Neu-Ulm Germany
510(k) number:	K954411

3.

Device:	Sono 5
Manufacturer:	Zimmer MedizinSysteme GmbH Junkersstrasse 9 89231 Neu-Ulm Germany
510(k) number:	K952536

c.) Device Description

The Soleoline has a clear contemporary color screen showing all parameters necessary for therapy as well as modern touch control. Individual program start configuration and clear, simple menu navigation make operation of the device easy and comfortable for users. 120 storage bins for individual program settings makes working with the Soleoline a lot easier. The compact design saves room in the practice and is highly suited for use in home visits. The combination of electrotherapy and ultrasound therapy in a single system enables the use of the established combination therapy. It is a prescription device administered to patients by a licensed healthcare provider in hospitals, post acute care facilities, nursing homes and outpatient clinics.

Soleoline is a device family consisting of Soleo Sono, Soleo Stim and Soleo SonoStim. Soleo Sono includes an ultrasound module, Soleo Stim includes a stimulation current therapy module and Soleo SonoStim includes a combination of a stimulation current module and an ultrasound module.
The stimulation current module is used for stimulation current therapy according to the standard medical practices. It offers multiple waveforms; Monophasic, High Voltage, Micro Current, Asymmetrical Biphasic, Symmetrical Biphasic, Interferential, Medium Frequency, Premodulated currents for nerve stimulation and muscle therapy for mono channel and dual channel operation. The regulated output of the current stimulation module may be chosen from Constant Current (CC) or Constant Voltage (CV).

The dual frequency ultrasound module (800kHz and 2.4MHz) offers two different size ultrasound heads, 1cm^2 and 5cm^2 and pulsed and continuous duty cycles.

At combination therapy (simultaneous procedure) the features for ultrasound can be used together with the different stimulation waveforms. All functions of the 0.8MHz and 2.4MHz ultrasound can be combined with the following waveforms:
Monophasic, High Voltage, Micro Current, Symmetrical Biphasic, Medium Frequency, Premodulated

The therapy menu helps the clinicians to assign the indications of each body region to the appropriate therapy program.

d.) Statement of indications for use

The indications for use of the proposed device are the same as those for the predicate devices
Ultrasound therapy:

1. Relief of pain, muscle spasms and joint contractures
2. Relief of pain, muscle spasms and joint contractures that may be associated with:
   - Adhesive capsulitis
   - Bursitis with slight calcification
   - Myositis
   - Soft tissue injuries
   - Shortened tendons due to past injuries and scar tissues
3. Relief of pain, muscle spasms and joint contractures resulting from:
   - Capsular tightness
   - Capsular scarring

Electrotherapy:

1. Relaxation of muscle spasm
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Muscle re-education
5. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
6. Maintaining or increasing range of motion
7. Symptomatic relief or management of chronic, intractable pain
8. Post-traumatic acute pain
9. Post-surgical acute pain

e.) Comparison of Technological Characteristics

General:

Feature	Zimmer Soleoline (Soleo Sono, Soleo Stim, Soleo SonoStim)	Chattanooga Vectra Genisys w/o EMG	Zimmer Galva 5	Zimmer Sono 5
Number of channels	2	2/4	2	-
Number of connections	2	2	1	-
Touch screen interface	+	-	-	-
Color LCD screen	+	+	-	-
Intended use	Ultrasound diathermy, Powered muscle stimulator, Ultrasound and muscle stimulator	Ultrasound and muscle stimulator	Powered muscle stimulator,	Ultrasound diathermy
Indications electrotherapy	- Relaxation of muscle spasm - Prevention or retardation of disuse atrophy - Increasing local blood circulation - Muscle re-education - Immediate post-surgical stimulation of calf	- Relaxation of muscle spasm - Prevention or retardation of disuse atrophy - Increasing local blood circulation - Muscle re-education - Immediate post-surgical stimulation of calf	- Relaxation of muscle spasm - Prevention or retardation of disuse atrophy - Increasing local blood circulation - Muscle re-education - Immediate post-surgical stimulation of calf muscles to prevent thrombosis	-

	muscles to prevent thrombosis - Maintaining or increasing range of motion - Symptomatic relief or management of chronic, intractable pain - Post-traumatic acute pain - Post-surgical acute pain	muscles to prevent thrombosis - Maintaining or increasing range of motion - Symptomatic relief or management of chronic, intractable pain - Post-traumatic acute pain - Post-surgical acute pain	- Maintaining or increasing range of motion	
Indications ultrasound therapy	- Relief of pain, muscle spasms and joint contractures - Relief of pain, muscle spasms and joint contractures that may be associated with: • Adhesive capsulitis • Bursitis with slight calcification • Myositis • Soft tissue injuries • Shortened tendons due to past injuries and scar tissues - Relief of pain, muscle spasms and joint contractures resulting from: • Capsular tightness • Capsular scarring	- Relief of pain, muscle spasms and joint contractures - Relief of pain, muscle spasms and joint contractures that may be associated with: • Adhesive capsulitis • Bursitis with slight calcification • Myositis • Soft tissue injuries • Shortened tendons due to past injuries and scar tissues - Relief of pain, muscle spasms and joint contractures resulting from: • Capsular tightness • Capsular scarring	-	- Relief of pain - Muscle spasm - Joint contractures
Prescriptive use	+	+	+	+
Maximum adjustable therapy time [min]	60	60	60	30
Modifiable Waveform Parameters	+	+	+	-
Power source(s)	Universal power supply: 100 - 240VAC, 50/60Hz	Onboard switchable power supply: 120/240VAC, 50/60Hz	120 VAC, 60Hz	120 VAC, 60Hz
Method of Line Current Isolation	Fuse – Two 2,0A Time Lag	Fuse – Two 5.6A Time Lag	Decoupling by mains transformer, Fuses, Electrical overcurrent limiter	N/A
Patient Leakage Current: Normal condition	< 1mA	69µA	< 1mA	< 1mA
Patient Leakage Current: Single fault condition	< 0.5mA	31µA	< 0.5mA	< 0.5mA

Number of Output Modes	8: Interferential, Premodulated, Monophasic, Medium Frequency, Asymmetrical Biphasic, Symmetrical Biphasic, High Volt, Microcurrent	10: Interferential, Premodulated, VMS, VMS Burst, Russian, Asymmetrical Biphasic, Symmetrical Biphasic, High Volt, Microcurrent, Direct Current	5: Diadynamic current, Medium Frequency, Monophasic, Biphasic symmetric, High voltage	-
Number of Output Channels	2	2 & 4 channel units	1	-
Synchronous or Alternating	Both	Both	Synchronous	-
Method of Channel Isolation	LAN spacings compliant with IEC 60601-1 isolation requirements	LAN spacings compliant with IEC 60601-1 isolation requirements, and protective software isolation	-	-
Regulated Current or Regulated Voltage?	Yes, both CC and CV	Yes, both CC and CV	Yes, both CC and CV	-
Software/Firmware/ Microprocessor Control?	+	+	+	+
Automatic Overload Trip?	+	+	+	+
Automatic No-load Trip?	-	-	-	-
Automatic Shut-Off?	+	+	+	+
Patient Override Control?	+	+	+	N/A
Indicator Display: On/Off Status Low Battery Voltage/Current Level	 + N/A +	 + N/A +	 + N/A +	 + N/A N/A
Compliance with Voluntary Standards?	Yes, IEC/EN 60601-1, IEC/EN60601-1-2, IEC/EN 60601-2-5, IEC/EN 60601-2-10,	Yes, IEC/EN 60601-1, IEC/EN60601-1-2, IEC/EN 60601-2-5, IEC/EN 60601-2-10,	Yes, IEC/EN 60601-1, IEC/EN60601-1-2, IEC/EN 60601-2-10,	Yes, IEC/EN 60601-1, IEC/EN60601-1-2, IEC/EN 60601-2-5
Compliance with 21 CFR 898	+	+	+	+
Dimensions (w x d x h) [cm]	32.2 x 23.4 x 13	28.9 x 32.4 x 22.2	45 x 32.5 x 14	3.25 x 4.5 x 1.4
Weight [kg]	2.1	3.2	5.7	6.8
Housing Materials and Construction	Molded PC-ABS plastic material with screw assembly construction	ABS/PC injection-molded top and bottom shells, Thermo-Plastic Elastomer (TPE) partial overmolding on top, Acryl lens. Top and bottom are secured together with machine screws.	Bottom and front: Polystyrene; Cover: steel sheet; Front panel: glass	Bottom and front: Polystyrene; Cover: steel sheet; Front panel: glass
Surge Mode	Ramp up:0.5 – 60s On Time:0 – 60s Ramp down:0.2 - 5s Off Time:0 – 60s	N/A	Ramp up:0.5 – 60s On Time:0 – 60s Ramp down:0.5s Off Time:0 – 60s	-

Output specifications:

Monophasic rectangular:

Specifications	New Device	Vectra Genisys	Galva 5M
Waveform	Monophasic	-	Biphasic symmetric
Shape	Rectangular	-	Rectangular
Maximum Output Voltage (+/- 20 %)	24.7V@500Ω 99.9V@2kΩ 180V@10kΩ	-	25V@500Ω 100V@2kΩ 200V@10kΩ
Maximum Output Current (+/- 20 %)	50mA@500Ω 50mA@2kΩ 12mA@10kΩ	-	50mA@500Ω 50mA@2kΩ 20mA@10kΩ
Pulse Width	200µs – 1500µs	-	200µs – 1500µs
Frequency [Hz]	0-1667	-	0-1667
Beat Frequency [Hz]	N/A	-	N/A
Symmetrical Phases	No	-	No
Phase Duration	200µs – 1500µs	-	200µs – 1500µs
Net Charge	75µC	-	75µC
Maximum Phase Charge	75µC	-	75µC
Maximum Current Density [mA/cm²]	3.9@500Ω	-	3.9@500Ω
Maximum Power Density [W/cm²]	0.097@500Ω	-	0.097@500Ω
Burst Mode	N/A	-	N/A
a. Pulses per burst [PPB]	N/A	-	N/A
b. Bursts per second [BPS]	N/A	-	N/A
c. Burst duration [BD]	N/A	-	N/A
d. Duty Cycle	N/A	-	N/A
ON Time	See surge mode point 28.	-	See surge mode point 28.
OFF Time	See surge mode point 28.	-	See surge mode point 28.
Additional Features	Polarity reversal: Selectable. positive, negative or alternating; switches after each minute	-	Polarity reversal: Selectable. positive, negative or alternating; switches after each minute

Microcurrent:

Specifications	New Device	Vectra Genisys	Galva 5M
Waveform	Microcurrent, monophasic	Microcurrent, monophasic	-
Shape	Rectangular	Rectangular	-
Maximum Output Voltage (+/- 20 %)	0.49V@500Ω 1.98V@2kΩ 10.20V@10kΩ	0.51V@500Ω 2V@2kΩ 10V@10kΩ	-
Maximum Output Current (+/- 20 %)	0.98mA@500Ω 0.99mA@2kΩ 1.02mA@10kΩ	1mA@500Ω 1mA@2kΩ 1mA@10kΩ	-
Pulse Width	1ms-10000ms	1ms-10000ms	-
Frequency [Hz]	0.1-1000	0.1-1000	-
Beat Frequency [Hz]	N/A	N/A	-
Symmetrical Phases	No	No	-
Phase Duration	0.5ms-5000ms.	0.5ms-5000ms	-
Net Charge	N/A (monophasic)	N/A (monophasic)	-
Maximum Phase Charge	5000µC	5000µC	-
Maximum Current Density [mA/cm²]	0.078@500Ω	0.026@500Ω	-
Maximum Power Density [W/cm²]	$0.4*10^{-4}$@500Ω	$0.1*10^{-4}$@500Ω	-
Burst Mode	N/A	N/A	-
a. Pulses per burst [PPB]	N/A	N/A	-
b. Bursts per second [BPS]	N/A	N/A	-
c. Burst duration [BD]	N/A	N/A	-
d. Duty Cycle	N/A	N/A	-
ON Time	See surge mode point 28.	N/A	-

OFF Time	See surge mode point 28.	N/A	-
Additional Features	N/A	N/A	-

Symmetric biphasic rectangular:

Specifications	New Device	Vectra Genisys	Galva 5M
Waveform	Biphasic symmetric	Biphasic symmetric	Biphasic symmetric
Shape	Rectangular	Rectangular	Rectangular
Maximum Output Voltage (+/- 20 %)	40V@500Ω 146V@2kΩ 150V@10kΩ	40V@500Ω 158V@2kΩ 200V@10kΩ	25V@500Ω 100V@2kΩ 200V@10kΩ
Maximum Output Current (+/- 20 %)	80mA@500Ω 73mA@2kΩ 15mA@10kΩ	80mA@500Ω 79mA@2kΩ 20mA@10kΩ	50mA@500Ω 50mA@2kΩ 20mA@10kΩ
Pulse Width	100µs -1000µs	20µs-1000µs	100µs-1500µs
Frequency [Hz]	0-1667	1-250	0-1667
Beat Frequency [Hz]	N/A	N/A	N/A
Symmetrical Phases	Yes	Yes	Yes
Phase Duration	50µs-500µs	10µs-500µs	50µs-750µs
Net Charge	0 (symmetric)	0 (symmetric)	0 (symmetric)
Maximum Phase Charge	80µC	80µC	75µC
Maximum Current Density [mA/cm²]	6.25@500Ω	2.08@500Ω	3.9@500Ω
Maximum Power Density [W/cm²]	0.25@500Ω	0.083@500Ω	0.097@500Ω
Burst Mode			N/A
a. Pulses per burst [PPB]	5-100	7	N/A
b. Bursts per second [BPS]	1-200	1 - 10	N/A
c. Burst duration [BD]	0.7-0.028s	0.7 - 0.028s	N/A
d. Duty Cycle	1 – 0.0042	0.7 - 0.28	N/A
ON Time	See surge mode point 28.	See additional features	See surge mode point 28.
OFF Time	See surge mode point 28.	See additional features	See surge mode point 28.
Additional Features	See definition surge mode	Cycle times of 4/4, 4/8, 7/7, 5/5, 4/12, 10/10, 10/20, 10/30, 10/50, continuous (On/Off)	See definition surge mode

Asymmetric biphasic rectangular:

Specifications	New Device	Vectra Genisys	Galva 5M
Waveform	Biphasic symmetric	Biphasic symmetric	-
Shape	Rectangular	Rectangular	-
Maximum Output Voltage (+/- 20 %)	48@500Ω 104V@2kΩ 153V@10kΩ	55V@500Ω 197V@2kΩ 200V@10kΩ	-
Maximum Output Current (+/- 20 %)	100mA@500Ω 52mA@2kΩ 15mA@10kΩ	110mA@500Ω 99mA@2kΩ 20mA@10kΩ	-
Pulse Width	20µs-1000µs	20µs-1000µs	-
Frequency [Hz]	1-331	1-250	-
Beat Frequency [Hz]	N/A	N/A	-
Symmetrical Phases	No	No	-
Phase Duration	20µs-1000µs positive 2000µs negative	20µs-1000µs positive 80µs-4000µs negative	-
Net Charge	0 (symmetric)	0 (symmetric)	-
Maximum Phase Charge	100µC	110µC	-
Maximum Current Density [mA/cm²]	6.25@500Ω	2.86@500Ω	-
Maximum Power Density [W/cm²]	0.25@500Ω	0.157@500Ω	-
Burst Mode			-
a. Pulses per burst [PPB]	7	7	-
b. Bursts per second [BPS]	1 - 10	1 - 10	-
c. Burst duration [BD]	0.7 - 0.028s	0.7 - 0.028s	-
d. Duty Cycle	0.7 - 0.0028	0.7 - 0.28	-
ON Time	See surge mode point 28.	See additional features	-

OFF Time	See surge mode point 28.	See additional features	-
Additional Features	See definition surge mode	Cycle times of 4/4, 4/8, 7/7, 5/5, 4/12, 10/10, 10/20, 10/30, 10/50, continuous (On/Off),	-

High Voltage:

Specifications	New Device	Vectra Genisys	Galva 5M
Waveform	High Voltage, monophasic symmetric	-	High Voltage, monophasic symmetric
Shape	Rectangular	-	Rectangular
Maximum Output Voltage (+/- 20 %)	122V@500Ω 180V@2kΩ 180V@10kΩ	-	125V@500Ω 200V@2kΩ 200V@10kΩ
Maximum Output Current (+/- 20 %)	250mA@500Ω 75mA@2kΩ 15mA@10kΩ	-	250mA@500Ω 100mA@2kΩ 20mA@10kΩ
Pulse Width	10µs-100µs	-	10µs-100µs
Frequency [Hz]	0-1961	-	0-1961
Beat Frequency [Hz]	N/A	-	N/A
Symmetrical Phases	No	-	No
Phase Duration	10µs-100µs	-	10µs-100µs
Net Charge	25µC	-	25µC
Maximum Phase Charge	25µC	-	25µC
Maximum Current Density [mA/cm²]	19.5@500Ω	-	19.5@500Ω
Maximum Power Density [W/cm²]	2.44@500Ω	-	2.44@500Ω
Burst Mode	N/A	-	N/A
a. Pulses per burst [PPB]	N/A	-	N/A
b. Bursts per second [BPS]	N/A	-	N/A
c. Burst duration [BD]	N/A	-	N/A
d. Duty Cycle	N/A	-	N/A
ON Time	See surge mode point 28.	-	See surge mode point 28.
OFF Time	See surge mode point 28.	-	See surge mode point 28.
Additional Features	Polarity reversal: Selectable. positive, negative or alternating	-	Polarity reversal: Selectable. positive, negative or alternating

Medium Frequency:

Specifications	New Device	Vectra Genisys	Galva 5M
Waveform	Medium Frequency	Medium Frequency	Medium Frequency
Shape	Sinusoidal, unmodulated	Sinusoidal, unmodulated	Sinusoidal, unmodulated
Maximum Output Voltage (+/- 20 %)	50V@500Ω 157V@2kΩ 153V@10kΩ	52V@500Ω 188V@2kΩ 200V@10kΩ	60V@500Ω 206V@2kΩ 200V@10kΩ
Maximum Output Current (+/- 20 %)	99mA@500Ω 77mA@2kΩ 15 mA@10kΩ	104mA@500Ω 94mA@2kΩ 20mA@10kΩ	120mA@500Ω 100mA@2kΩ 20mA@10kΩ
Pulse Width	N/A	N/A	N/A
Frequency [Hz]	2000-8000	2000-10000	5000
Beat Frequency [Hz]	N/A	N/A	N/A
Symmetrical Phases	Yes	Yes	Yes
Phase Duration	N/A	N/A	N/A
Net Charge	0 (symmetric)	0 (symmetric)	0 (symmetric)
Maximum Phase Charge	15.9µC	16.6µC	7.64µC
Maximum Current Density [mA/cm²]	4.38@500Ω	2.6@500Ω	9.4@500Ω
Maximum Power Density [W/cm²]	0.123@500Ω	0.129@500Ω	0.562@500Ω
Burst Mode	N/A	N/A	
a. Pulses per burst [PPB]	N/A	N/A	17.5-835
b. Bursts per second [BPS]	N/A	N/A	0.1-250Hz
c. Burst duration [BD]	N/A	N/A	3.5ms-167ms
d. Duty Cycle	N/A	N/A	N/A

ON Time	See surge mode point 28.	See additional features	See surge mode point 28.
OFF Time	See surge mode point 28.	See additional features	See surge mode point 28.
Additional Features	See definition surge mode	Cycle Times of 5/5, 4/12, 10/10, 10/20, 10/30, 10/50, Continuous (On/Off)	See definition surge mode

Premodulated:

Specifications	**New Device**	**Vectra Genisys**	**Galva 5M**
Waveform	Medium Frequency	Medium Frequency	-
Shape	Sinusoidal, modulated	Sinusoidal, modulated	-
Maximum Output Voltage (+/- 20 %)	50V@500Ω 162V@2kΩ 166V@10kΩ	52V@500Ω 188V@2kΩ 200V@10kΩ	-
Maximum Output Current (+/- 20 %)	100mA@500Ω 81mA@2kΩ 17mA@10kΩ	104mA@500Ω 94mA@2kΩ 20mA@10kΩ	-
Pulse Width	12.5µs-500µs	10µs-500µs	-
Frequency [Hz]	2000-8000	2000-10000	-
Beat Frequency [Hz]	1-200	1-200	-
Symmetrical Phases	Yes	Yes	-
Phase Duration	6.25µs-250µs	5µs-250µs	-
Net Charge	0 (symmetric)	0 (symmetric)	-
Maximum Phase Charge	15.9µC	16.6µC	-
Maximum Current Density [mA/cm²]	6.25@500Ω	2.6@500Ω	-
Maximum Power Density [W/cm²]	0.25@500Ω	0.129@500Ω	-
Burst Mode	N/A	N/A	-
a. Pulses per burst [PPB]	N/A	N/A	-
b. Bursts per second [BPS]	N/A	N/A	-
c. Burst duration [BD]	N/A	N/A	-
d. Duty Cycle	N/A	N/A	-
ON Time	See surge mode point 28.	See additional features	-
OFF Time	See surge mode point 28.	See additional features	-
Additional Features	See surge mode point 28.	Cycle Times of 5/5, 4/12, 10/10, 10/20, 10/30, 10/50, Continuous (On/Off)	-

Interferential:

Specifications	**New Device**	**Vectra Genisys**	**Galva 5M**
Waveform	Interferential	Interferential	-
Shape	Sinusoidal, channel modulation	Sinusoidal, channel modulation	-
Maximum Output Voltage (+/- 20 %)	52V@500Ω 164V@2kΩ 103V@10kΩ	52V@500Ω 172V@2kΩ 200V@10kΩ	-
Maximum Output Current (+/- 20 %)	103mA@500Ω 82mA@2kΩ 10mA@10kΩ	100mA@500Ω 86mA@2kΩ 19mA@10kΩ	-
Pulse Width	N/A	N/A	-
Frequency [Hz]	2000-8000	2000-10000	-
Beat Frequency [Hz]	1-200	1-200	-
Symmetrical Phases	Yes	Yes	-
Phase Duration	N/A	N/A	-
Net Charge	0 (symmetric)	0 (symmetric)	-
Maximum Phase Charge	16.4µC	15.9µC	-
Maximum Current Density [mA/cm²]	6.25@500Ω	2.6@500Ω	-
Maximum Power Density [W/cm²]	0.25@500Ω	0.129@500Ω	-
Burst Mode	N/A	N/A	-
a. Pulses per burst [PPB]	N/A	N/A	-
b. Bursts per second [BPS]	N/A	N/A	-
c. Burst duration [BD]	N/A	N/A	-

d. Duty Cycle	N/A	N/A	-
ON Time	N/A	N/A	-
OFF Time	N/A	N/A	-
Additional Features	N/A	N/A	-

Ultrasound Specification

Parameter	New Device	Vectra Genisys	Sono 5
Frequencies	0.8 and 2.4 MHz	1 and 3.3MHz	0.8 and 3 MHz
Intensity	0-3.0 W/cm²	0-3.0W/cm²	0-3.0W/cm²
Wave form	Pulsed, continuous	Pulsed, continuous	Pulsed, continuous
Pulse Rate	20Hz, 50Hz, 100Hz	100Hz	20Hz, 50Hz
Duty Cycle	1:1, 1:2, 1:3, 1:5, 1:10	1:1, 1:2, 1:5	1:2, 1:5
Treatment Time	0-30 Minutes	0-30 Minutes	0-30 Minutes
Applicator Sizes	1cm², 5cm²	1cm², 2cm², 5cm², 10cm²	1.5 cm², 5 cm²
Maximum output	5 cm²: 0-6.9W (800kHz), 0-7.1W (2.4MHz) 1 cm²: 0-1W (800kHz), 0-0.6W (2.4MHz)	10 cm²: 0-20 W (1MHz), 0-10 W (3.3 MHz) 5 cm²: 0-10 W, (1 and 3.3 MHz) 2 cm²: 0-4 W, (1 and 3.3 MHz) 1 cm²: 0-2 W (3.3 MHz only)	5 cm²: 0-10W (800kHz), 1.5 cm²: 0-1W (2.4MHz)
BNR	4.3:1 or less	5.0:1 or less	6.0:1 or less
ERA	5 cm²: 2,30 cm² (0,8MHz) 2,38 cm² (2,4MHz) 1 cm²: 1,08 cm² (0,8MHz) 0,54 cm² (2,4MHz) all values ±20%	10 cm²: 8.5 cm², ±1.5 5 cm²: 4.0 cm², ±1.0 2 cm²: 1.8 cm², +0.2/- 0.4 1 cm²: 0.8 cm², +0.2/-0.4	5 cm²: 3.3 cm², 1.5 cm²: 1.0 cm², all values ±20%
Applicator Temporal Peak / Average Ratio	1:1, 2:1, 3:1, 5:1, 10:1	2:1, 5:1, 9:1	2:1, 5:1

f.) Summary Comparison with predicate devices

The Soleo Sono, Soleo Stim and Soleo SonoStim share the same intended use and the same or similar basic characteristics and features as the predicate devices. In addition, any differences in their technological characteristics are explained to demonstrate in this submission that these differences do not raise any new questions of safety and effectiveness.

g.) Non-clinical Tests Performed

Validation documentation, product testing and a comparison of the technical characteristics and features according to relevant standards were provided to demonstrate that Soleo Sono, Soleo Stim and Soleo SonoStim are safe and effective in its intended use.

h.) Conclusion Substantial Equivalence

Drawn from the comparison between the predicate devices and the Soleoline devices it demonstrates that the Soleoline devices are as safe and effective as the predicate devices and therefore are substantially equivalent to the compared devices on the basis of similarities in operating principles, intended use and functional performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Zimmer MedizinSysteme GmbH
% TÜV SÜD America, Incorporated
Mr. Alexander Schapovalov
1775 Old Highway 8
New Brighton, Minnesota 55112-1891

AUG 7 2012

Re: K121059
Trade/Device Name: Soleo Sono, Soleo Stim, and Soleo SonoStim
Regulation Number: 21 CFR 890.5860
Regulation Name: Ultrasound and muscle stimulator
Regulatory Class: II
Product Code: IMG, IPF, IMI, GZJ, LIH
Dated: July 18, 2012
Received: July 23, 2012

Dear Mr. Schapovalov:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Zimmer
MedizinSysteme

Zimmer Medizinsysteme GmbH
Junkersstraße 9
D-89231 Neu-Ulm

Tel. 0731 / 9761-0
Fax 0731 / 9761-118

info@zimmer.de
www.zimmer.de

4. Indications for Use Statement

Indications for Use Soleo Sono:

Ultrasound therapy:

Relief of pain, muscle spasms and joint contractures
Relief of pain, muscle spasms and joint contractures that may be associated with: • Adhesive capsulitis • Bursitis with slight calcification • Myositis • Soft tissue injuries • Shortened tendons due to past injuries and scar tissues
Relief of pain, muscle spasms and joint contractures resulting from: • Capsular tightness • Capsular scarring

Indications for Use Soleo Stim:

Electrotherapy:

For Medium Frequency, Monophasic Currents, Biphasic Symmetric Currents and High Voltage

Relaxation of muscle spasm
Prevention or retardation of disuse atrophy
Increasing local blood circulation
Muscle re-education
Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
Maintaining or increasing range of motion

For IFC, Premodulated, Microcurrent, Asymmetric Biphasic Currents and Symmetric Biphasic Currents

Symptomatic relief or management of chronic, intractable pain
Post-traumatic acute pain
Post-surgical acute pain

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121059

Indications for Use Soleo SonoStim:

Ultrasound therapy:

Relief of pain, muscle spasms and joint contractures
Relief of pain, muscle spasms and joint contractures that may be associated with: • Adhesive capsulitis • Bursitis with slight calcification • Myositis • Soft tissue injuries • Shortened tendons due to past injuries and scar tissues
Relief of pain, muscle spasms and joint contractures resulting from: • Capsular tightness • Capsular scarring

Electrotherapy:

For Medium Frequency, Monophasic Currents, Biphasic Symmetric Currents and High Voltage

Relaxation of muscle spasm
Prevention or retardation of disuse atrophy
Increasing local blood circulation
Muscle re-education
Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
Maintaining or increasing range of motion

For IFC, Premodulated, Microcurrent, Asymmetric Biphasic Currents and Symmetric Biphasic Currents

Symptomatic relief or management of chronic, intractable pain
Post-traumatic acute pain
Post-surgical acute pain

Prescription Use ____X____ AND/OR Over-the-counter Use _____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121059